displaying seven treatment attributes: medication, therapy, school involvement, caregiver behavior training, physician management, provider communication and out-of-pocket costs. Every attribute was operationalized into 3 possible levels. Within each task, caregivers selected one best and one worst attribute. A scale-adjusted latent-class (SALC) analysis was conducted to account for variability in the consistency of responses. **RESULTS:** Our study population of 164 caregivers were on average 42 years old (SD 8.7), predominantly female (95%), white (65%), married (61%), college-educated (73%), and 20% had a child who was diagnosed with ADHD for ≤1year. Based on the aggregate results, using medication everyday was the most preferred treatment attribute (coefficient=2.41, p<0.001). Three latent classes (i.e. segments) that best described the data were identified, and the scale factor included in the model was significant (p<0.001). The 3 segments comprised 28%, 27%, and 45% of our study population. Segment 1 has the strongest preference for 'medication' (coefficients=3.69 –4.34, all p<0.001) while Segment 2 displayed the least preference for medication (coefficients= -1.49 – -3.36, all p<0.001). Segment 3 was most cost-avoidant (coefficients=-2.13 – -6.11, all p<0.001) but had the strongest preference for 'school involvement' (coefficients=0.63 – 2.58, all p<0.05). **CONCLUSIONS:** This study demonstrated variation in caregivers' priorities for ADHD treatment attributes. A better understanding of preferences for evidence-based treatment options can enhance patient-centered care. By utilizing SALC, our study reduces the likelihood of misclassification error.

PMH46

QUALITATIVE STUDY OF PATIENTS' PREFERENCES FOR BIPOLAR DEPRESSION TREATMENT

Ng-Mak DS[1], Poon JL[2], Rajagopalan K[1], Kleinman L[3], Roberts L[2], Revicki DA[2], Loebel A[4]
[1]*Sunovion Pharmaceuticals, Inc, Marlborough, MA, USA,* [2]*Evidera, Bethesda, MD, USA,* [3]*Evidera, Seattle, WA, USA,* [4]*Sunovion Pharmaceuticals, Inc, Fort Lee, NJ, USA*

OBJECTIVES: Patient focus groups were conducted to identify the most important clinical attributes and outcomes of pharmacological treatments for bipolar depression influencing patients' treatment adherence decisions. Qualitative results will guide the development of a quantitative discrete choice experiment to determine patient preferences and willingness to trade-off between medication characteristics. **METHODS:** Adults clinically diagnosed with bipolar I disorder, recently depressed, previously/currently treated with antipsychotics, and not currently suicidal were recruited from two clinical sites. Following an IRB-approved (E&I Review Services) protocol, inclusion criteria, and semi-structured, open-ended discussion guide, focus groups lasting 90-minutes were conducted to discuss patients' expectations and experiences towards treatment safety and efficacy. Focus groups recordings were transcribed, a data coding dictionary developed, and ATLAS.ti used for qualitative data analysis. **RESULTS:** From the two focus groups conducted (n=8 each; Total N=16; mean age 47.9±6.4 years; 68.8% female, mean time since diagnosis 15.7±11.4 years; mean length of atypical antipsychotic use 4.7±4.6 years), participants were most concerned with treatment efficacy, expecting a medication to balance the "highs and lows" of bipolar symptoms and providing "clarity" (control of thoughts and actions). One in 4 expected symptom improvements within 2-3 weeks of treatment initiation, and would tolerate side effects and less desirable features, as long as these did not outweigh treatment benefits. Side effects mentioned spontaneously and rated most highly by participants as influencing treatment initiation and persistence decisions were weight gain (n=8, 50.0%) and sedation/fatigue (n=7, 43.8%). To manage side effects, most (n=7, 43.8%) reported self-treatment by reducing dosage or discontinuing without medical consultation. **CONCLUSIONS:** Treatment efficacy, faster onset in terms of symptom improvement, less weight gain, and less severe sedation/fatigue were identified as most important outcomes determining patients' treatment decisions. Based on qualitative results, identified treatment attributes will be included in a quantitative discrete choice experiment to determine patients' preferences for bipolar depression pharmacological treatments.

PMH47

RELATIVE EFFICACY AND TOLERABILITY OF VORTIOXETINE VERSUS APPROVED ANTIDEPRESSANTS FOR MAJOR DEPRESSIVE DISORDER: A META-REGRESSION OF CLINICAL TRIALS

Diamand F[1], Danchenko N[1], Brignone M[1], Rive B[1], Perez V[2], Ereshefsky L[3], Francois C[4], Merikle E[5]
[1]*Lundbeck S.A.S. Paris Fr, EU, Paris, France,* [2]*Analysis Group, Inc., Montreal, QC, Canada,* [3]*Parexel International, Glendale, CA, USA,* [4]*Lundbeck LLC, Deerfield, IL, USA,* [5]*Takeda Pharmaceuticals International, Inc, Deerfield, IL, USA*

OBJECTIVES: Vortioxetine, a novel antidepressant exhibiting a multimodal mechanism of action, was approved for the treatment of adults with major depressive disorder (MDD). This extension study of a recently published meta-analysis (Llorca et al. Curr Med Res Opin 2014;30(12):2589-606) compares the efficacy and tolerability of vortioxetine with seven commonly used antidepressants marketed in the US. **METHODS:** Indirect comparisons using meta-regression, an extension of random-effects meta-analysis, were performed using data from 54 double-blind, placebo-controlled Phase 3 pivotal studies identified in a systematic review (N= 18,312 patients). To ensure study comparability, only experimental drug and placebo arms were included in primary analyses. Study-level standardized effect sizes were regressed on active treatment to compare efficacy and tolerability of vortioxetine with branded (levomilnacipran, vilazodone, desvenlafaxine) and generic (duloxetine, escitalopram, sertraline, venlafaxine) antidepressants. Efficacy was defined as change from baseline on the Montgomery-Asberg Depression Scale or Hamilton Depression Rating Scale after 2 months (6-12 weeks) of treatment. Tolerability was defined as the withdrawal rate due to any adverse event. **RESULTS:** Standardized mean differences for vortioxetine compared with the selected antidepressants (negative estimates favor vortioxetine) were: duloxetine, 0.10 (95% confidence interval [CI]: -0.12, 0.32); escitalopram, -0.04 (95% CI: -0.32, 0.24); sertraline, -0.02 (95% CI: -0.39, 0.34); venlafaxine, 0.14 (95% CI: -0.11, 0.39); levomilnacipran, -0.05 (95% CI: -0.28, 0.19); vilazodone, -0.23 (95% CI: -0.53, 0.06); and desvenlafaxine, 0.04 (95% CI: -0.16, 0.23). Significantly lower withdrawal rates were observed for vortioxetine versus sertraline, venlafaxine, and desvenlafaxine (all P<0.05). No statistically significant difference in withdrawal rates was observed between vortioxetine and duloxetine, escitalopram, levomilnacipran, or vilazodone. **CONCLUSIONS:** These findings show that vortioxetine offers a comparable combination of efficacy and tolerability in MDD to other antidepressants marketed in the US.

PMH48

A REVIEW OF CLINICAL OUTCOME ASSESSMENTS USED IN FDA APPROVED DRUG LABELS FOR MENTAL HEALTH CONDITIONS

Pompilus FA[1], Lindberg-Springs S[1], Seoane-Vazquez E[2]
[1]*Massachusetts College of Pharmacy & Health Sciences, Boston, MA, USA,* [2]*MCPHS University, Boston, MA, USA*

OBJECTIVES: Clinical outcome assessments (COAs) are clinician-reported outcomes (ClinROs), patient-reported outcomes (PROs), observer-reported outcomes (ObsROs), and performance outcomes (PerfROs) tools used to assess the patient's symptom, impact, and overall mental state. PRO measures, specifically developed to capture the patients' perspective without clinician interpretation, are considered an approved means to support labeling by the Food and Drug Administration (FDA). This study aims to identify the extent to which COAs were used to support label claims and to identify the prevalence of PRO specific measures in mental health drugs approved by the FDA in the period 2006-2014. **METHODS:** New drugs used to treat mental health conditions approved by the FDA from 2006-2014 were identified and labels were retrieved from using the Drugs@FDA database. The "Indications and Usage" and "Clinical Studies" sections of each label were reviewed and relevant indications and concordant COA data was extracted and categorized by type using PROQOLID. **RESULTS:** A total of 20 FDA-approved drugs for use in mental health conditions were identified. Of these, 18 labels included clinical study data and 14 labels used the results of COAs to support 19 indications; major depressive disorder (n=5), schizophrenia and/or schizoaffective disorder (n=5), attention deficit hyperactivity disorder (n=3), bipolar mania (n=2), insomnia (n=2), seasonal affective disorder (n=1), depressive episodes associated with bipolar I disorder (n=1). Clinical studies included 32 COAs used 47 different times to support drug/indication labeling; 39 ClinROs, 4 ObsROs, and 4 PerfROs (none employed PRO measures). COAs were used to measure primary efficacy endpoints (n=41), to establish safety (n=2) and to determine study eligibility (n=7) (not mutually exclusive). Thirteen out of 14 labels demonstrated efficacy by using a COAs. **CONCLUSIONS:** All mental health drug labels approved by the FDA since 2006 utilized clinical outcome assessments to support drug efficacy and labeling, however PROs were underutilized.

PMH49

IMPACT OF MAJOR DEPRESSIVE DISORDER ON PATIENT FUNCTIONALITY AND WORK PERFORMANCE IN EMERGING MARKETS

Reznik AE[1], Sudharshan L[1], Stephens JM[1], Shelbaya A[2], Pappadopulos E[2], Haider S[3], Lin I[1], Gao C[1]
[1]*Pharmerit International, Bethesda, MD, USA,* [2]*Pfizer, Inc, New York, NY, USA,* [3]*Pfizer Inc, Groton, CT, USA*

OBJECTIVES: This review was designed to synthesize information about the impact of major depressive disorder (MDD) on functionality, work performance, and potential stigma in the emerging markets of Brazil, China (including Taiwan) and Russia. **METHODS:** Studies indexed in MEDLINE (2004-2014) and abstracts from relevant conferences were screened with search terms including "depression/MDD," "productivity/employment," "functionality," and "stigma." **RESULTS:** Sixteen studies were extracted for Brazil, 18 for China and 5 for Russia. There was significant study heterogeneity in the study populations and outcome measures in the literature. The negative correlation of MDD with functionality and work performance was evident across countries. In Brazil, depression increased the risk of unemployment by 39% (OR 1.39; 95% CI 1.15-1.67) in one study and was significantly predictive of worse hrQoL among subpopulations sampled in other studies (P ≤ .001). Depression was associated with decreased work performance (OR 0.91; 95% CI 0.87-0.95) in Chinese enterprises. In Taiwan, MDD patients experienced an average 5.8-61 sick-leave days annually. Depressed (vs non-depressed) Chinese had a higher risk of impairment in activities of daily living (RR 2.20-4.29; 95% CI 1.33-8.86). A Russian study reported that depression impacted employment for 31.7% of urban-dwelling adults; 12.2% reduced working hours, 17.1% became unemployed and 24.4% took an average 74 ± 54 sick-leave days annually. Stigma caused by cultural and social factors was an obstacle to help-seeking, MDD diagnosis and treatment in China and Russia but not in Brazil. **CONCLUSIONS:** MDD is correlated with impaired functionality and work performance in Brazil, China and Russia. Stigma specific to national environment should be addressed to remove barriers to MDD treatment. Future longitudinal inquiry is needed to comprehensively evaluate the consequences of MDD. New research investigating the impact of MDD and its treatment on functionality and work performance among working adults without comorbidities is needed in emerging markets.

PMH50

FACTORS AFFECTING HEALTH-RELATED QUALITY OF LIFE IN INDIVIDUALS WITH DEPRESSION

Shah D, Anupindi VR, Vaidya V, Goodman M
University of Toledo, Toledo, OH, USA

OBJECTIVES: It has been known that depression is associated with significant impairments in health-related quality of life (HRQOL). However, few studies have evaluated HRQOL dysfunction in both physical and mental health domains. This study examined the factors, namely demographic, socio-economic and health-related factors affecting the physical and mental health domains of HRQOL in individuals suffering from depression. **METHODS:** This retrospective, observational cross-sectional study used data from the 2011 Medical Expenditure Panel